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Atty. Docket No. 081356-0156

1616  
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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Hideaki NOMURA et al.  
Title: POWDERY PREPARATION FOR MUCOSAL  
ADMINISTRATION CONTAINING POLYMERIC  
MEDICINE  
Appl. No.: 09/720,970  
Filing Date: 1/3/2001  
Examiner: Sharmila S. Gollamudi  
Art Unit: 1616

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop DD  
Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(d), before payment of the issue fee.

04/19/2004 CCHAU1 00000131 09720970

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**RELEVANCE OF EACH DOCUMENT**

A Supplementary European Search Report dated February 13, 2004, is attached with four of the listed documents. Listed document WO 90/09780 was previously submitted with the Information Disclosure Statement filed on April 3, 2001. All of the listed documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

**STATEMENT**

The undersigned hereby states in accordance with 37 CFR §1.97(e)(1) that each item of information contained in this supplemental information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to filing of this Statement.

**FEE**

A fee in connection with submission of a supplemental information disclosure statement under 37 CFR §1.97(d) in the amount of \$180.00 in accordance with 37 CFR §1.17(p) is attached.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 16 April 2004

By S. A. Bent

FOLEY & LARDNER LLP  
Washington Harbour  
3000 K Street, N.W., Suite 500  
Washington, D.C. 20007-5143  
Telephone: (202) 672-5404  
Facsimile: (202) 672-5399

Stephen A. Bent  
Attorney for Applicant  
Registration No. 29,768

APR 16 2004

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449B/PTO  
**INFORMATION DISCLOSURE  
 STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 1

**Complete if Known**

Application Number	09/720,970
Filing Date	1/3/2001
First Named Inventor	Hideaki Nomura
Group Art Unit	1616
Examiner Name	Sharmila S. Gollamudi
Attorney Docket Number	081356-0156

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Patent MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	4,613,500		SUZUKI et al.	09-23-1986	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A2		JP 08198772 (Abstract only)		KIRIN BREWERY CO LTD	08-06-1996		

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A3	K. AIKAWA et al., "Drug Release from pH-response Polyvinylacetal Diethylaminoacetate Hydrogel, and Application to Nasal Delivery," International Journal of Pharmaceuticals 168 (1998) 181-188.	
	A4	M. DITTGEN et al., "Acrylic Polymers, A Review of Pharmaceutical Applications," S.T.P. Pharma Sciences vol. 7 no. 6 (1997) 403-437.	

Examiner Signature

Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.